

Patent
Docket No. CYM-025
24738-7003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Roy Ostgaard, et al

Serial No.: 09/156,952

Filed: September 18, 1998

For: SAMPLE VIAL FOR USE IN
PREPARING CYTOLOGICAL SPECIMEN

Group Art Unit: 1743

Examiner: Patricia K. Bex

APPEAL BRIEF TRANSMITTAL

Box: Board of Patent Appeal
and Interference
Commissioner for Patents
Washington, D.C. 20231

Sir,

Transmitted herewith is Appeal Brief (11 pages) in triplicate, for the above-identified application.

The items checked below are appropriate.

- ☒ Appeal Brief Fee:
- ☒ Large Entity Fee of \$320.00; or
- ☐ Small Entity Fee of \$160.00.
- ☐ Applicant(s) claim Small Entity Status under 37 CFR § 1.27.
- ☒ Petition for Extension of Time with 1 month extension fee (1 page)

CERTIFICATE OF FACSIMILE TRANSMISSION (37 C.F.R. § 1.6 (d))

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Respectfully submitted,

BINGHAM McCUTCHEN LLP

Dated: March 10, 2003

By:

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23639

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: |) | Group Art Unit: 1743 |
| |) | |
| Ostgaard et al. |) | Examiner: Patricia K. Bex |
| |) | |
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| PREPARING CYTOLOGICAL |) | |
| SPECIMEN |) | |

APPEAL BRIEF-CFR 1.192

**ATTN: Board of Patent Appeals
and Interferences**
Assistant Commissioner
for Patents
Washington, D.C. 20231

Dear Sir:

This Brief is in furtherance of the Notice of Appeal, filed in this case on December 10, 2002, and contains the following items in the order indicated below as required by CFR 1.192:

- I. Real Party in Interest
- II. Related Appeals and Interferences
- III. Status of Claims
- IV. Status of Amendments
- V. Summary of Invention
- VI. Issues
- VII. Grouping of Claims
- VIII. Arguments
- IX. Appendix of Claims Involved in the Appeal

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I. Real Party in Interest

The real party in interest in this appeal is Cytyc Corporation of Boxborough, Massachusetts, a corporation organized and existing under laws of the Commonwealth of Massachusetts.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes claims 1-26. Of these claims, claims 1-8, 10, and 12-26 are pending, and the remaining claims 9 and 11 have been cancelled. Of the pending claims, claims 1-8, 10, and 12-26 stand rejected, leaving no claims allowed. The claims on appeal are claims 1-8, 10, and 12-26.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Invention

Although the invention should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of one preferred embodiment in order to aid in understanding the invention.

The invention, as defined in the claims on appeal, is directed to a sample vial 10 for use in an automated test apparatus. The sample vial 10 generally includes a body 12, a cap 14 releasably engagable with the body 12, and a seal 24 disposed between the body 12 and cap 14.

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(See Fig. 1). The cap 14 comprises a torque pattern 38 formed by a plurality of radially disposed ribs 16, thereby allowing the cap 14 to be installed on or released from the body 12 using a rotatable interface that engages the radially disposed ribs 16. The body 12 comprises anti-rotation lugs 18 that react against proximate structure of an automated test apparatus when the body 12 is installed in the proximate structure to facilitate automated removal and installation of the cap 14 on the body 12. Specifically, the anti-rotation lugs 18 have a geometry that provides control over the rotation and penetration depth (i.e., translation) of the body 12 relative to the bore 52 of an interface 54 (illustrated in Fig. 7A) and the bore 62 of a vial sleeve 64 (illustrated in Fig. 7B).

For example, after the vial 10 has been filled with a sample, the body 12 can be disposed within the bore 52 the interface 54, with the anti-rotation lugs 18 abutting against the vertical faces 58 of ramps 56 when clockwise rotation of the body 12 is attempted during installation of the cap 14. In addition, the body 12 can be disposed within the bore 62 of a vial sleeve 64 illustrated in Fig. 7B, with the anti-rotation lugs 18 being received in the slots 66. Thus, counter-clockwise rotation of the body 12 is prevented when the cap 12 is removed in order to dispense the sample, and clockwise rotation of the body 12 is prevented when the cap 12 is reinstalled on the body after the sample has been dispensed.

Each of the anti-rotation lugs 18 has a longitudinally disposed surface that extends radially outwardly from the outer surface of the body 12. This longitudinally disposed surface has features that facilitate proper interaction with the ramps 56 of the unidirectional interface 54 and the slots 66 of the vial sleeve 64. First, the longitudinally disposed surface is flat to maximize the area that comes in contact with the vertical face 58 of the respective ramp 56.

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Second, the longitudinally disposed surface has a lowermost edge that is substantially perpendicular to the outer surface of the body 12, so that the anti-rotation lugs 18 properly engage the bottom surfaces of the ramps 56 and slots 66. Third, the lowermost edge of the longitudinally disposed surface is closer to the open end of the body 12 than to the closed end, allowing the body 12 to be properly inserted within the bore 52 of the interface 54 and the bore 62 of the vial sleeve 64.

VI. Issues

Whether claims 1-8, 10, and 12-26 are unpatentable under 35 U.S.C. §103 as being obvious over U.S. Patent No. 5,894,733 ("Brodner") in view of U.S. Patent No. 5,855,289 ("Moore")?

VII. Grouping of Claims

Applicants make no statement as to the grouping of claims 1-8, 10, and 12-26.

VIII. Arguments

Applicant respectfully submits that the Examiner erred in rejecting claims 1-8, 10, and 12-26 under 35 U.S.C. §103 as being obvious over Brodner in view of Moore. The Examiner indicated that Brodner discloses all of the elements recited by claim 1 with the exception of a torque pattern with a plurality of radially disposed ribs (See Office Action, dated September 11, 2002, page 3, lines 4-6), and then used Moore to provide this missing element. Applicants submit, however, that the teachings of Brodner and Moore, even if properly combined, would not result in the claimed invention.

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Brodner is directed to a specimen vial 10 and labeled sleeve 12 that, in combination, purport to overcome difficulties apparently associated with labeling containers stored at cryogenic temperatures. (col. 1, lines 7-12, 23-26; Fig. 2). The vial 10 is cylindrically shaped and includes vertically spaced ridges 34 disposed about its exterior surface 30. (col. 2, lines 61-63; Figs. 1, 2, and 4.) (Brodner Figure 2 (left-hand drawing) seemingly misidentifies the ridges 34 by using reference designator 10). The sleeve 12 also includes vertically spaced ridges 58 disposed about its interior surface 52. (col. 3, lines 30-32, Fig. 2). The vial 10 is inserted into sleeve 12, resulting in a "nested engagement," wherein the sleeve ridges 58 are in "pressing engagement" with the vial ridges 34. (col. 3, lines 42-47).

The sleeve 12 operates similarly in relation to the tray 16. Specifically, the sleeve 12 includes vertically spaced ridges 56 disposed about its exterior surface 44. (col. 3, lines 28-30). The aperture opening 66 of the tray 16 includes vertically spaced ridges 68 that are in "pressing engagement" with the ridges 56 of the exterior surface 44 of the sleeve 12 when the sleeve 12, with the vial 10 nested therein, is placed in the aperture 62 of the tray. (col. 3, lines 34-41).

To establish obviousness, it must be found that the differences between the claimed invention and the prior art would have been obvious to a person having ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). Applicants believe that the differences between the claim 1 invention and the teachings of Brodner and Moore would not have been obvious to a person having ordinary skill in the art.

The teachings of Brodner were characterized by the Examiner as follows:

Brodner teaches the use of polypropylene (column 3, lines 11-13) container body 12 comprising an outer surface, an open end and closed bottom end (Fig. 2). The vial comprising a plurality of integral anti-rotation lugs 56 about the outer surface of the cylindrical body (Figs. 2-3). Wherein the anti-rotation lug comprises a flat,

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longitudinally disposed surface extending radially outwardly from the body outer surface, which is substantially perpendicular to the body of the vial. Moreover, the surface of the plurality of anti-rotation lugs is accessible when the cap 24 of container 14 is engaged with the neck of vial 12 (Fig. 4). (Office Action, page 2, paragraph 4) (emphasis added).

Applicants respectfully submit, however, that the cap 24 is not engagable with the sleeve structure 12, and the lowermost edges of the ridges 56 are not substantially perpendicular to the outer surface of the sleeve structure 12, as required by claim 1. Assuming that the sleeve structure 12 can be characterized as a container body as the Examiner concludes, the cap 24 is not releasably engagable with the container body (i.e., the sleeve structure 12), as required by claim 1. Rather, the cap 24 is releasably engagable with the specimen container 10. (see col. 2, lines 49-52). Although the Examiner refers to Fig. 4 of Brodner for support that the cap 24 is engaged with the neck of the sleeve structure 12, this figure clearly shows that the cap 24 is actually engaged with the neck of the specimen container 10. Thus, there is no teaching or suggestion in Brodner that a cap can be releasably engaged with a sleeve structure that houses a vial. Moore fails to supply this teaching.

In addition, even if the ridges 56 of the sleeve structure 12 could be characterized as a anti-rotation lugs that extend from the outer surface of the container body, as the Examiner concludes, the lower edges of these ridges 56 are not perpendicular to the outer surface of the sleeve structure 12. Rather, they appear to be tapered or beveled, as clearly shown in Fig. 2 of Brodner.

Notably, the geometry of the lowermost edge of the anti-rotation lug 18 is a relevant aspect of Applicants' invention. For example, requiring that each anti-rotation lug 18 have a lowermost edge that is substantially perpendicular to the outer surface of the body 12 ensures that

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the vial 10 will not (1) penetrate too deeply into the bores 52, 62, thereby causing the vial 10 to jam in the apparatus and frustrate the operation of the automated test apparatus; and (2) axially translate to an improper position when in the vial sleeve 64. (See Amendment and Response, dated October 19, 2001, page 8, line 1 to page 9, line 7).

Significantly, if the lowermost edges of the ridges 56 of Brodner were made to be perpendicular to the outer surface of the sleeve structure 12, the objective of Brodner would be defeated. It is an established principle that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See In re Gordon, 733 F.2d 900 (Fed. Cir. 1984). Brodner indicates that the purpose of the ridges 56 is to provide a locking engagement with the ridges 68 of the tray 16 when the combination of the sleeve structure 12 and vial 10 is slid into the aperture 62 of the tray 16. Brodner specifically states:

The ridges 56 provide locking engagement of the combination 14 when the combination 14 is inserted into a receiving aperture 62 of the tray 16. Upper edges 64 extending about an opening 66 of the aperture 62 preferably contain a plurality of small ridges 68 which produce a locking type action when the ridges 56 are in pressing engagement thereagainst or between. (col. 3, lines 34-41).

It is clear, however, that if the lowermost edges of the ridges 56 were perpendicular to the outer surface of the sleeve structure 12, they would most likely abut against the uppermost edges of the tray ridges 68 when attempting to slide the sleeve structure 12 within the tray aperture 16. As a result, the sleeve structure 56 could not be mounted within the tray 16, or at the least, there would be difficulty in doing so without manual intervention by the user. Thus, the lowermost edges of sleeve structure ridges 56 must be tapered or beveled for the Brodner device to properly operate, and there would be no suggestion or motivation to modify them.

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Thus, the differences between the sample vial of claims 1-8, 10, and 12-26 and the teachings of Brodner and Moore would not have been obvious to a person having ordinary skill in the art. As such, Applicants respectfully submit that claims 1-8, 10, and 12-26 are patentable over the prior art of record.

IX. Appendix of Claims Involved in the Appeal

1. (Seven times amended) A sample vial for use in an automated test apparatus, the sample vial comprising:

a body comprising an outer surface, an open end, a closed end, and at least one anti-rotation lug about said body outer surface, the anti-rotation lug comprising a generally flat, longitudinally disposed surface extending radially outwardly from said body outer surface, the longitudinally disposed surface comprising a lowermost edge that is substantially perpendicular to said body outer surface, the lowermost edge located closer to the open end than to the closed end;

a cap releasably engagable with said body, said cap comprising an outer surface and a torque pattern on said cap outer surface, said torque pattern comprising a plurality of radially disposed ribs; and

a seal disposed between said body and said cap so as to be capable of forming a substantially fluid-tight seal therebetween.

wherein both of the flat surface and the lowermost edge of the at least one anti-rotation lug is accessible when the cap is engaged with the body for reacting against proximate structure of the automated test apparatus when installed therein to facilitate at least one of automated removal and installation of the cap.

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2. The sample vial of claim 1 wherein said body comprises a translucent material.
3. The sample vial of claim 1 wherein said body comprises polypropylene.
4. The sample vial of claim 1 wherein said cap further comprises knurling along an outer perimeter thereof.
5. The sample vial of claim 1 wherein said cap comprises polypropylene.
6. The sample vial of claim 1 wherein said seal comprises a multicomposite material.
7. The sample vial of claim 1 wherein a substantially fluid-tight seal between said body and said cap is formed when between about 5 and 50 inch-pounds of torque is applied.
8. The sample vial of claim 7 wherein a substantially fluid-tight seal between said body and said cap is formed when about 20 inch-pounds of torque is applied.
10. (Amended) The sample vial of claim 1 wherein said torque pattern comprises six radially disposed equi-spaced ribs.
12. (Amended) The sample vial of claim 1 wherein said body comprises a plurality of circumferentially-disposed lugs.
13. The sample vial of claim 12 wherein said body comprises six equi-spaced circumferentially-disposed lugs.
14. The sample vial of claim 12 wherein said plurality of circumferentially-disposed lugs are disposed proximate said open end.
15. (Amended) The sample vial of claim 1 wherein said body further comprises fluid level indicia disposed on said outer surface thereof.

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16. The sample vial of claim 15 wherein said fluid level indicia comprises a frosted annular band disposed circumferentially about said body outer surface.
17. The sample vial of claim 15 wherein said fluid level indicia comprises at least one fill line.
18. The sample vial of claim 17 wherein said fluid level indicia comprises an upper fill line and a lower fill line.
19. The sample vial of claim 1 wherein said cap comprises a first alignment marker said body comprises a second alignment marker, wherein said first and second alignment markers indicate a fluid-tight seal when at least aligned.
20. The sample vial of claim 19 wherein said cap may be removed from said body by the application of less than about 25 inch-pounds of torque, when said first marker is at least aligned with said second marker.
21. The sample vial of claim 1 wherein said seal is disposed within said cap.
22. The sample vial of claim 1 wherein said cap further comprises a first screw thread, said body further comprises a second mating screw thread, said cap and said body being releasably engagable by means of said first screw thread and said second screw thread.
23. The sample vial of claim 1 wherein said body further comprises sample indicia.
24. The sample vial of claim 23 wherein said sample indicia comprises a bar code.
25. The sample vial of claim 1 wherein said body further comprises a flange proximate said open end.
26. The invention of claim 1 wherein the proximate structure is selected from the group consisting of a storage tray and a vial sleeve.

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Respectfully submitted,

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Dated: 3-10-03

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